

## § 493.1806

## 42 CFR Ch. IV (10–1–11 Edition)

(2) CMS imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when CMS or CMS's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.*

(1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions, (CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) CMS may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* CMS bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by CMS, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or non-compliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other CMS agents, and to CMS.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that CMS hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* CMS may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in § 493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

### § 493.1806 Available sanctions: All laboratories.

(a) *Applicability.* CMS may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* CMS may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at § 493.1832.

(2) State onsite monitoring as set forth at § 493.1836.

(3) Civil money penalty, as set forth at § 493.1834.

(d) *Civil suit.* CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]